PART III: INTERIM FORMATTING INSTRUCTIONS FOR NEW AND COMPETING CONTINUATION CCSG APPLICATIONS

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This part provides formatting instructions that supplement those on the Grant Application Form PHS 398 (rev. 5/95). It is in the particular interest of applicants that the review of complex grant proposals be as trouble-free as possible. Adherence to these instructions will greatly assist peer reviewers in identifying sections of the application and in matching them with the corresponding review criteria listed in Part II, 5.0 of these guidelines.

In general, all pertinent information needed for evaluation should be included in the body of the application; however, applicants should be as concise as possible. Material not essential to making a center's best case for funding should not be included, since it dilutes the main message and distracts reviewers from the major points of the application. If the applicant wishes to submit appendix materials, see section 12.0.

Page Limitations. These limits apply only to the narrative parts of each section. This includes descriptive abstracts, budget justifications, objectives, goals, rationales, accomplishments, tables, figures, charts, etc. This does not include budget pages, biographical sketches, publication lists or lists of grants. Please also note that page limits are, by definition, maxima and are not meant also to suggest the minimum length of sections.

1.0 Face Page

The face page of the Grant Application Form PHS 398 (rev. 5/95) should be completed as indicated in the application kit. The "principal investigator" is the cancer center director; the "applicant institution" is the fiscally responsible institution of which the cancer center is a part.

2.0 Description

A description, limited to the space provided on page 2 of the PHS 398 form, should provide a summary of the CCSG-related organization and research programs of the cancer center, and a brief description of the request for support through the CCSG.

3.0 Table of Contents

This should contain correct pagination for all major sections and subsections of the application.

4.0 Overall Description of the Cancer Center

Limit 20 pages. This section should provide reviewers with a general perspective on the center's activities. A brief history and broad overview of the center, especially its research efforts, serve to place the entire application in context. A simple map best illustrates the geography of the center, the location of its major activities, and the physical relationship of any affiliated institutions to the main campus. This is

also the place to summarize the center's major scientific thrusts, the principal research opportunities that it is trying to exploit, and how the various scientific efforts fit together in the center. A brief discussion of several of the most important discoveries occurring in the center during the last period of support will help reviewers understand what the center's investigators consider their most important achievements. After reading this section a reviewer previously unfamiliar with the center should have a fair grasp of what the center is, what it does, and what the center considers its most important recent discoveries.

5.0 Essential Characteristics of the Cancer Center
Limit 20 pages.

5.1 Cancer Focus
Refer to Part I, 5.1 and Part II, 5.2.3.1.

5.2 Institutional Commitment
Refer to Part I, 5.2 and Part II, 5.2.3.2. It is helpful to include a schematic showing the center's position within the institution(s) in relation to other organizational components (e.g., schools, departments, institutes, or the equivalent).

5.3 Organizational Capabilities
Refer to Part I, 5.3 and Part II, 5.2.3.3. A diagram(s) is useful in illustrating a center's programmatic structure, administrative organization, advisory groups and decision-making committees and processes.

5.4 Facilities
Refer to Part I, 5.4 and Part II, 5.2.3.4.

5.5 Center Director
Refer to Part I, 5.5 and Part II, 5.2.3.5.

5.6 Interdisciplinary Coordination and Collaboration
Refer to Part I, 5.6 and Part II, 5.2.3.6.

6.0 Standard Cancer Center Information

These Summaries (see Attachment for instructions and formats) itemize for easy reference the center's research programs, shared resources, base of funded research projects, patient information and clinical research protocols.

- Summary 1 - Research Programs, Members and Shared Resources
- Summary 2 - Existing Funded Projects
- Summary 3 - Patients
- Summary 4 - Clinical Research Protocols

7.0 Research Programs

Limit 25 pages per program; centers that include most or all clinical research in one Program may exceed the limitation for this Program. Refer to Part I, 9.0 and Part II, 3.1 and 5.2.2.

- **Title page** of the Program with the name(s) of the Program Leader(s) and the Program Code (used in Summary 2 of the Standard Cancer Center Information).

- A brief **description** of the Program using page 2 of the PHS 398 Form.

- A **budget** for the percent effort of the first and future years for the Program Leader(s) using the standard budget pages provided in the PHS 398 form (Note: a level of effort must be included for each Program Leader whether or not salary is requested).

- A **budget narrative justification** based on the specific role of the Program Leader(s) in facilitating interdisciplinary research important to cancer.

- **Biographical sketches** of Program Leader(s) (Use PHS 398 Form).

- A list of the **externally funded research projects** of the Program by member, project and funding source (e.g., a subset of Summary 2) (See Part I, 9.3 and Part II, 3.1.1). If the Program has a clinical orientation, reference can be made to Summary Form 4 of the Standard Cancer Center Information for more detailed information about individual clinical protocols.

- The **members** of the Program in alphabetical order, with their departmental and institutional affiliation as well as their academic rank (or equivalent). Highlight any members of the program who are proposed to receive staff investigator salary support by indicating for each person the percent effort for which CCSG support is being requested.

- The **scientific goals** of the Program and how the interests, expertise and research approaches of the Program members are being used to achieve them.

- The most significant **scientific accomplishments** of the Program and the ways in which the cancer center facilitated or enabled these accomplishments.

- A selected list of Program-related **publications** from the last project period. Indicate those that particularly illustrate the inter- and intra-programmatic collaborations.

8.0 Non-programmatically Aligned Research Members.

No more than 2 pages. List the non-aligned members in alphabetical order and include their departmental affiliations, areas of expertise and research interests, in a few sentences. If a significant proportion of the membership (i.e., greater than 10%) is not aligned with any of the center's research Programs, describe the strategies used to take advantage of their scientific expertise in furthering the research objectives of the center.

9.0 Narratives and Budget for All CCSG Categorical Requests

For each categorical request noted under the headings below (e.g., Senior Leadership, Developmental Funds, etc.), follow the instructions in the PHS 398 form for the "First 12-month Budget Period" and the summary budgets for the "Entire Proposed Project Period." Budget justifications for each budget component (e.g., personnel, supplies, etc.) should focus only on what the CCSG is intended to support.

Note also for individuals in key positions, a percent effort must be declared and a narrative provided even if no salary is requested. Each categorical request should be included in the application in the order noted below:

9.1 Senior Leadership

No more than 1 page per senior leader. See Part II, 3.2.1 and 5.2.4. Prepare one consolidated budget of percent efforts for all Senior Leaders. Narrative justifications for Senior Leaders should carefully describe their roles. Each narrative should be followed by a biographical sketch (PHS 398 Form).

9.2 Program Leaders of Research Programs (budget pages only)

See Part II, 3.2.1 and 5.2.2. Provide only a single consolidated budget that lists all Program Leaders in the center and their percent efforts. This is merely a consolidation of the separate budgets provided and justified in Section G. DO NOT provide any narratives.

9.3 Staff Investigators

No more than 1 page per staff investigator. See Part II, 3.2.2 and 5.2.13. Prepare a consolidated budget accompanied by separate short narrative justifications and a biographical sketch for each staff investigator. The narrative should specify the formal research program(s) of the Center in which the staff investigator participates.

9.4 Program Planning and Evaluation

No more than 5 pages. See Part II, 3.2.3 and 5.2.5. Provide a consolidated budget and narrative justifications for each planning and evaluation activity. The narrative should first summarize how past CCSG funds were used, what was accomplished, and how future needs will be met with the requested budget. If the center employs an outside advisory group, include a consolidated list of these individuals with titles and institutional affiliations. Attach their biographical sketches or curricula vitae.

9.5 Developmental Funds

No more than 15 pages. See Part II, 3.2.4 and 5.2.6. Prepare a composite budget that includes all developmental fund categories being requested. Also provide individual budgets by category with separate narrative justifications. Narratives should summarize how past CCSG developmental funds were used, what was accomplished with them and how the new request will be used to meet future needs. If a pilot project program is proposed, describe how the projects are reviewed for scientific merit and selected for funding.

9.6 Rebudgeting Authority (competing renewals only)

No more than 5 pages. See Part I, 10.2 and Part II, 5.2.9. For reporting actions taken by the Cancer Center within the 25% rebudgeting authority, the Center needs to report only the cumulative effect of rebudgeting into or out of any budget component (e.g., flow cytometry core, developmental funds) over the course of the entire grant (e.g., five years). Do not report changes by category having a cumulative change less than 10%. In reporting changes include the dollar amount of the rebudgeting, and, briefly, the rationale for the rebudgeting action, and what was accomplished by the action.

9.7 Administration

No more than 5 pages. See Part II, 3.2.5 and 5.2.12. The administrative budget request and narrative should be limited to and justified in terms of the specialized research needs of the cancer center and not be duplicative of parent institution(s) responsibilities.

9.8 Shared Resources

No more than 15 pages for each shared resource, on average. Note: centers present resource requests in various ways. Some prefer to group several core components into a single categorical request (e.g., Immunology, Cell Biology). The 15-page limitation is intended to accommodate bundled requests of this kind. Requests for most individual core resources should require much less than the 15-page limit). See Part II, 3.2.6 and 5.2.10. Appropriate budget information, data and narrative justifications should be prepared for each resource. The biographical sketch or C.V. of the key resource director(s) or manager(s) should follow the narrative justification. Narratives and accompanying data should provide or address:

- A brief **description** of the resource using page 2 of the PHS 398 form.
- The **importance** of the resource in relation to the scientific needs and objectives of the cancer center.
- The current **extent of use by each** peer-reviewed, funded member of the cancer center during a recent 12-month period. Discuss any projected increases or decreases in use of the resource based on the scientific needs of the Center.

- The total percent of **overall use** of the shared resource by peer reviewed, funded members (i.e., the sum of the use as a percent of the total use of the resource). If the resource is not used primarily or exclusively by cancer center members, provide additional information, as necessary for peer review.

- The **capacity** of the resource if it were functioning full-time at peak efficiency.

- Any **policies** of the resource relating to access, services and costs, e.g., chargeback systems.

- **Cost-effectiveness** of the resource (when applicable) relative to other options for obtaining the service.

All shared resources critical to the clinical research needs of the center (e.g., biostatistics, centralized protocol management office) should be presented last, so they can be reviewed in sequence with the next sections, "Protocol Review and Monitoring System" followed by "Protocol-specific Research Support."

9.9 Protocol Review and Monitoring System (PRMS)
No more than 10 pages exclusive of list of protocols. See Part I, 10.5; Part II, 3.2.7 and 5.2.7.

- **Budget and Justification**. Include a budget page and a narrative budget justification.

- Describe the **criteria for selection of the membership** of the committee. List the members of the committee and their expertise. The biographical sketches of these individuals should be included at the end of this section.

- Describe the **procedures for scientific review and monitoring** of cancer clinical trial protocols. Describe the criteria and process for submission of institutional clinical trial protocols to the committee for review and approval; the process for review of all cancer clinical research protocols of the institution; the review criteria that are used to assess scientific rationale, study design, expected accrual rates, adequacy of biostatistical input and feasibility for completion within a reasonable time period; the criteria used for monitoring ongoing institutional protocol research to evaluate scientific progress, including reasonable accrual rates, to ensure that the scientific aims of the study can be completed; and the criteria for terminating a clinical protocol. Describe whether the committee has ever terminated any protocols, and for what reason.

- Describe the **process and criteria used for prioritizing** the activation of cancer clinical protocols at the institution with respect to scientific merit and patient availability.

- Describe PRMS **operations relative to the Institutional Review Board** (IRB) approval process with emphasis on the complementarity of the two entities and absence of overlap or duplication.

- Provide a list of all **Institutional protocols** (i.e., studies that have not received external review) that have been reviewed by the PRMS for scientific merit in a recent 12-month period. List those protocols that were approved and activated, approved but not yet activated, deferred for revision, and disapproved. Indicate for the same 12-month period how many protocols in the institution were monitored for progress and performance and list those that were closed, along with the reason for closure. Peer reviewers will select a sample of the listed protocols for detailed review prior to the site visit. Protocols should <u>not</u> be included in or appended to the CCSG application. For approved, activated protocols, provide descriptive information about the protocol including target accruals and accruals to date using Standard Cancer Center Information, Summary 4, Clinical Research Protocols.

9.10 Protocol-specific Research Support
No more than 4 pages. See Part II 3.2.8 and 5.2.8. Provide a budget justification and narrative for why these funds are needed for support of innovative, pilot, Phase I clinical research protocols.

10.0 Inclusion of Minorities and Women in Clinical Trials (NIH Policy)
No more than 4 pages. See Part II, 4.0 and 5.2.14.

- **Demographics**. Provide summary information showing the national demographics of the patient population, by majority group and each minority group and both genders, with the number and percent given for each. Provide similar demographic breakdowns for the cancer patient population in the primary catchment area of the center, as well as for the cancer patient population treated at the cancer center.

- **Accrual.** Provide summary accrual information from the most recent 12-month period by majority group and each minority group and by gender in the following two areas: (a) the therapeutic clinical trials conducted at the cancer center, and (b) the NON-therapeutic trials conducted at the cancer center. Relate this information to the demographic information provided above.

- **Deficiencies and Corrective Actions**. If there are any proportional deficiencies in the accrual of women and minorities to therapeutic and non-therapeutic trials relative to the opportunities as defined by the demographics of the center's catchment area, note:

- Any general policies of the **institution** designed to help with this problem.
- Unavoidable circumstances that impede accrual of women and minorities (e.g., a high proportion of non-eligible patients).
- Any actions planned or being taken by the **center**, based on careful analyses of the population, which demonstrate a clear, "good faith" effort to correct deficiencies that are potentially avoidable.

11.0 Other Support

"Other Support" information should be included in this section following the PHS 398 format and instructions. Other support information should be submitted **only** for all key personnel for whom a **level of effort** is requested on the CCSG, irrespective of whether or not salary is also requested.

12.0 Appendices

After the application has been submitted, the applicant should contact the Scientific Review Administrator (SRA) to discuss the inclusion of any appendix materials that are important to peer review. Only materials approved by the SRA will be included in appendices and used by peer review.

13.0 Review Materials to be Available at the Site Visit

- Biographical sketches of all (research) cancer center members. A complete set of biographical sketches facilitates the review particularly if it is made available to the Scientific Review Administrator for use during the pre-site visit meeting of reviewers.
- Institutional protocols that have been reviewed by the center's Protocol Review and Monitoring Committee.
- Log books or other records of use for all shared resources.
- Minutes or reports of external and internal advisory committees, retreats, etc., involved in the planning and evaluation process for the center.
- An updated Summary 2, Existing Funded Projects from the Standard Cancer Center Information, and using the same format if desired, a separate list of grants and contracts pending peer review, approval and funding. It is suggested that these items be made available to the SRA for use during the pre-site visit meeting.